REMARKS

This is in response to the Official Action mailed February 13, 2002 for the above-captioned application. Applicants request an extension of time sufficient to make this paper timely, and enclose the appropriate fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

Reconsideration of the application in view of the remarks herein is respectfully requested.

The Examiner rejected claims 3, 4, 6 and 9-29 under 35 USC § 112, second paragraph. The Examiner asserts that the claims are indefinite because "one cannot say which compound is being claimed." The Examiner has not provided any explanation as to why this assertion is made.

It is well established that claims are to be considered definite where the person skilled in art, having read the specification, can determine their scope. *Andrew Corp. v. Gabriel Electronics Co.*, 6 U.S.P.Q. 2d 2010, 2023 (Fed. Cir. 1988). Further, it is incumbent on the Examiner to establish that one having ordinary skill in the art would not have been able to determine the scope of protection defined by the claim when read in light of the specification. *In re Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (POBAI 1989). The Examiner has plainly failed to meet this burden. Furthermore, Applicants respectfully submit that the claims are fully understandable to a person skilled in the art.

Claim 3 recites a chemical compound which includes first and second hsp-binding moieties, connected by a linker. As set forth in claim 3, both of these hsp- binding moieties are ansamycin antibiotics. The linker is just that, some additional portion of the structure which connects one ansamycin antibiotic hsp-binding moiety to the other. The same limitations appear in each of the other independent claims. The Examiner has not explained why a person skilled in the art would have any difficulty recognizing an ansamycin antibiotic or whether or not a linker was present in a compound. Furthermore, Applicants point out that a "claim to a chemical compound is not indefinite merely because a structure is not presented or because a partial

structure is presented." MPEP § 2173.05(t). Thus the Examiner has failed to meet the burden imposed by *Cordova* and other cases and the rejection should be withdrawn.

The Examiner has also rejected claims 13-29 under 35 USC § 112, first paragraph, asserting that utility in treating cancers generally (as opposed to treating some specific types of cancers) must be proven because "no compound has ever been found that can treat cancers generally, even though massive efforts have been directed towards this end." Applicants understand this assertion to relate to the ability of a common compound to treat a significant range of types of cancer, rather than an assertion that treatment of every individual must be expected to be successful. In this context, Applicants provide additional information concerning the basis for the assertion of general applicability.

While exemplary compounds of the present invention have not yet undergone substantial clinical testing, a number of tests have been carried out on a monomeric ansamycin compound, 17-allylamino-geldanamycin (17-AAG), which is mentioned in the specification on Page 8, line 15, and other hsp90 inhibitors. These show that these compounds are efficacious in a variety of tumor types other than breast cancer, ovarian cancer, pancreatic cancer and gastric cancer (the cancer's mentioned in the specification), including tumors which do not over express HER kinase. For example, Yang et al. (Exhibit A), report inhibition of glioma (brain tumor) cells with 17-AAG. Okabe et al. (Exhibit B) reports *in vivo* activity of herbimycin A (an ansamycin antibiotic) against leukemia cells. Kelland *et al* (Exhibit C, JNCI 91: 1940, 1999) achieved tumor cytostasis in two human colorectal carcinomas, HT29 and BE for the duration of drug treatment with 17-AAG. Burger *et al* (Exhibit D Proc. AACR, 41: Abstract # 2844, 2000) reported potent effects of 17-AAG against a melanoma xenograft and, interestingly, preliminary data from the London arm of the 17-AAG trial indicates that melanoma (2/6 objective responses) may be a responsive tumor (Exhibit E Banerji *et al*, Proc. ASCO, Abstract # 326, 2001) 17-AAG has also been used in studies with prostate cancers, and it has been shown that this administration resulted in dose-dependent inhibition of androgen-dependent and -independent prostate cancer xenografts. (Exhibit F Solit et al., *Clin. Cancer Res.* 8: 986-993, 2002). 17-AAG

has also been shown to enhance paclitaxel-mediated cytotoxicity in lung cancer cells (Exhibit G Nguyen et al, *Ann. Thorac. Surg.* 72: 371-379, 2001); and to modulate metastasis phenotypes in non-small cell lung cancer (Exhibit H Nguyen et al., *Ann. Thorac. Surg.* 70: 1853-60, 2000). Thus, the efficacy of compounds that bind to the hsp90 receptor span a wide range of unrelated cancers. Thus, applicants submit that they should properly be granted the generic claim as presented.

Notwithstanding the foregoing arguments and evidence, which Applicants believe overcome the rejection under 35 USC § 112, first paragraph, Applicants have added claims 30-34 which recite cancer subsets. Support for the cancers identified in the claims can be found throughout the specification and on Page 8, lines 9-12.

In view of the foregoing amendments and arguments, Applicants submit that all claims are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully submitted,

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